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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,183	04/06/2004	Nabil Dib	61643.00002	7387

7590

06/23/2005

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EXAMINER

AHMED, AAMER S

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/820,183

**Applicant(s)**

DIB, NABIL

**Examiner**

Aamer S. Ahmed

**Art Unit**

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/6/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Objections***

Claim 1 is objected to because of the following informalities: The phrase "and a needle for selectively moving to extend . . ." is unclear. It is suggested that the phrase "adapted" be inserted. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Mann ('857).

As to Claim 1, Mann describes a medical device comprising a catheter having a catheter lumen with a proximal end and a distal end; and a needle for selectively moving to extend from the distal end of the catheter lumen to a first position to take the biopsy and to a second position within the catheter lumen, said needle having a first port between the distal end of the needle and the proximal end of the needle. (See Figure 1).

Furthermore, as to Claim 2, Mann describes a sheath having sheath lumen through which the catheter is selectively moved. (See Figure 1).

In addition, as to Claim 3 Mann discloses that the device includes a means for selectively restricting relative movement between the sheath and the catheter. (See Figure 1).

Art Unit: 3763

Moreover, as to Claim 8, Mann describes that the device further includes a second port in fluid communication with the first port. (See Column 5).

Thus Mann reasonably appears to teach and disclose every element of claims 1-3 and 8.

Claims 9-13 and 16, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Altman ('887).

As to Claims 9 and 19, Altman describes a medical device comprising a catheter having a catheter lumen with a proximal end and a distal end; and a needle for selectively moving to extend from the distal end of the catheter lumen to a first position, and to a second position within the catheter lumen, said needle having a first port, 432 between the distal end of the needle and the proximal end of the needle for selectively opening and closing, a sheath having a sheath lumen through which the catheter is selectively moved, 424 and a driver for selectively moving the needle with one or more predefined force, acceleration and velocity, 420. (See Figures 4a and 4b).

In addition, as to Claim 10, Altman discloses that the medical device includes a sheath with a sheath through which the catheter is selectively moved, 424. (See Figures 4a and 4b).

Furthermore, as to Claims 11 and 20 Altman teaches the presence of a means for selectively restricting relative movement between the sheath and the catheter, 422. (See Figures 4a and 4b).

Art Unit: 3763

Also, as to Claim 12 Altman describes a driver for selectively moving the needle with one or more of a predefined force, a predefined acceleration and a predefined velocity to penetrate the material, 420. (See Figure 4a).

Moreover, as to Claim 13 Altman discloses that, the driver selectively rotates the needle. (See Figure 5 and Column 7).

In addition, as to Claim 16 Altman teaches the presences of a second port in fluid communication with the first port and a supply of the fluid, 502. (See Figure 5).

Thus Altman reasonably appears to teach and disclose every element of claims 9-13.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 3763

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4, 6 and 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Mann ('857) in view of Zadini ('361). Mann discloses the medical device as described above in reference to claim 1. However Mann fails to disclose that the medical device includes: a driver for moving the needle, a sensor or that the sensor is on the needle.

Zadini describes a similar medical device with a driver, a sensor on the needle, 952. (See Figure 53).

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the medical device of Mann by adding the driver and sensor as taught by Zadini in order to obtain a more controllable biopsy injection catheter.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mann ('857) in view of Altman ('887). Mann and Zadini describe the medical device as described in reference to Claim 1, along with a driver. They fail to disclose that the driver selectively rotates the needle.

Altman discloses that, the driver selectively rotates the needle. (See Figure 5 and Column 7).

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the medical device of Mann by adding the rotating needle r as taught by Altman in order to obtain a more controllable biopsy injection catheter.

Art Unit: 3763

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman ('887) in view of Zadini ('361). Altman describes the devices as described above in reference to Claim 9. However Altman fails to disclose a sensor, nor that the sensor is on the needle.

Zadini describes a similar medical device with, a sensor on the needle, 952. (See Figure 53).

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the medical device of Altman by adding the driver and sensor as taught by Zadini in order to obtain a more controllable injection catheter.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann ('857) in view of Altman ('887). Mann describes A medical device for taking a biopsy of material, comprising a catheter having a catheter lumen with a proximal end and a distal end; a needle for selectively moving to extend from the distal end of the catheter lumen to a first position to take the biopsy and to a second position within the catheter lumen a sheath having a sheath lumen through which the catheter is selectively moved. (See Figure 1). Mann fails to disclose a driver for selectively moving the needle with one or more of a predefined force, a predefined acceleration and a predefined velocity to penetrate the material and a means for selectively restricting relative movement between the sheath and the catheter.

Altman does describe a driver for selectively moving the needle with one or more of a predefined force, a predefined acceleration and a predefined

Art Unit: 3763

velocity to penetrate the material, 420 and a means for selectively restricting relative movement between the sheath and the catheter, 422. (See Figures 4a and 4b).

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the medical device of Altman by adding the driver and means for restricting relative movement as taught by Altman in order to obtain a more controllable biopsy injection catheter.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 4953558 A	Akerfeldt
U.S. Pat. No. 5989197 A	Avaltroni
U.S. Pat. No. 6273861 B1	Bates
U.S. Pat. No. 6156006 A	Brosens et al.
U.S. Pat. No. 5368045 A	Clement et al.
U.S. Pat. No. 6106524 A	Eggers et al.
U.S. Pat. No. 6835193 B2	Epstein et al.
U.S. Pat. No. 6203556 B1	Evans et al.
U.S. App. No. 20020151850 A1	Ferguson et al.
U.S. Pat. No. 5564436 A	Hakkyet al.
U.S. Pat. No. 5810836 A	Hussein et al.



Art Unit: 3763

U.S. Pat. No. 5611352 A Kobren et al.

U.S. App. No. 20020099307 A1 Krause et al.

U.S. Pat. No. 6117130 A Kung

U.S. Pat. No. 5964757 A Ponzi

U.S. Pat. No. 6287301 B1 Thompson et al.

U.S. Pat. No. 5599300 A Weaver et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 3763

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A handwritten signature in black ink, appearing to read "N. Lucchesi", with a stylized, cursive script.

NICHOLAS D. LUCCHESI  
SUPERVISORY PATENT EXAMINER  
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